

6 November 2015

Karen DeSalvo, MD
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Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. DeSalvo,

Thank you for the opportunity to comment on “Draft 2016 Interoperability Standards Advisory”. We believe focus on key standards and implementation guidance is essential to realize a safe and effective nationwide strategy for health information technology and for proper capture, management, exchange and use of health data/information, including safeguards for patient care, clinical practice, privacy and security.

Key Point: We remain seriously concerned that ONC’s proposed guidance seem(s) to offer little consideration for truth (authenticity) and trust (assurance) as baselines/foundations for what is proposed to achieve interoperability. This is particularly evident in the case of primary use (clinical care, interventions and decision making) where health data/records must maintain fidelity to source content regardless of intentional transformation to/from exchange artifacts (e.g., HL7 v2 messages and CDA/CCDA documents). We believe the integrity of clinical practice and most importantly, patient safety, are placed at risk by the numerous recommendations of this Advisory, particularly those which imply or assert the requirement for data/record content transformation in the course of exchange.

Regards,

Gary Dickinson
Director, Healthcare Standards, CentriHealth
Co-Chair, Health Level Seven (HL7) Electronic Health Record (EHR) Work Group

[This cover letter and comment document were submitted electronically via the ONC website.]

General Comments

[Basic elements of some of the following comments were submitted with the previous Standards Advisory but which, in our view, remain unresolved in the 2016 draft.]

1. Interoperability is Purpose-Based

Interoperability can only be described, measured and achieved if first understood as to its scope (what) and purpose (why).

What: are we striving to make interoperable?

- A) Personal health and healthcare data/records?
- B) Provider healthcare data/records?
- C) Integration of data/records received from an external source?
- D) Health data/record flows: point to point and/or end to end?
- E) Data/record flows integral to process (work) flows?

Why: for what purpose?

- F) To support primary use: clinical care, interventions and decision making?
- G) To support secondary use: most everything else?
- H) To ensure integrity of the clinical process, of the health system?
- I) To ensure patient safety?
- J) To render a facsimile representation of data/records (e.g., fax, photocopy, PDF) that is human readable?
- K) To render a computable representation of data/records that is software process-able?
- L) To render a precise copy of the original source provider health record: i.e., provider business, and evidentiary record for legal purposes?

Please make this explicit.

Standards Advisory, Page 6: "When one standard or implementation specification is listed as the 'best available,' it reflects ONC's current assessment and prioritization of that standard or implementation specification for a given interoperability need."

2. Primary and Secondary Use = "A Given Interoperability Need"

The Advisory makes no reference to primary or secondary use nor their specific distinction as "a given interoperability need".

- 2A.** Please revise the Advisory to include advice for "best available" standards for both primary and secondary use.
- 2B.** Also, make explicit the reference to each designated standard as to whether it is intended to support primary or secondary use or both.

3. Interoperability is Based on Fitness for Use

True interoperability ensures fitness for use (purpose) at each ultimate point of health data/record access/use. The following table shows the challenging paradigm of data/record exchange between heterogeneous systems and the risk to fitness (for use/purpose) posed by data transformations. Double transformations often occur during the course of exchange when health data/record content is transformed to/from exchange artifacts (e.g., to/from HL7 v2

messages and CDA/CCDA documents) – once by the source/sending system and once again by the receiving system.

Use	Purpose	Health Record Content Exchange			Post Exchange Fit for Use?
		Source	→ → →	Receiver	
Primary	Clinical Care, Interventions and Decision Making	Without Transformation (maintains/ensures fidelity to source)			YES
		With Transformation(s)			Often NO
Secondary	Most Everything Else	With Transformation(s)			Typically YES

- 3A.** As with the 2015 version, the Advisory makes no mention of “fitness for use” but one would assume this to be a minimum threshold of achievement to support both primary and secondary use.

Per our Comment 2A, the Advisory should be explicit regarding “fitness for use” in cases of primary and/or secondary use – and note this as a post-exchange (and testable) achievement of interoperability.

- 3B.** Most all of what is offered in Advisory recommendations for “best available” standards – vocabulary/terminology, code sets, exchange artifacts – presume you must transform to/from these standard artifacts to achieve interoperability. While singly/doubly transformed health data/record content may be sufficient for certain secondary use it often falls short of competence and the proper level of trust assurance required for primary use. *This is a key issue for (indeed threat to) the integrity of clinical practice and mostly importantly, to patient safety.*

The Advisory should make explicit which of the enumerated “best available” standards explicitly (or effectively) require single or double transformations and thus aren’t designed to deliver unaltered (authentic) source health data/record content across points of exchange.

4. Interoperability is Based on Truth and Trust

Truth = factual, authentic = the facts are evident

Trust = assurance, reliance = I am assured, I trust, thus I rely on

The achievement of interoperability is primarily about truth and trust – as evidenced at each downstream point of access/use – to the ultimate primary or secondary user of health data/records.

Truth	as evidence for	Trust
✓ Identity is verified	→ → →	<ul style="list-style-type: none"> • Belief (believability) • Certainty • Reliance • Traceable to a “source of truth” • Based on – and manifest in – evidence presented
✓ Source, origination and provenance is evident		
✓ Signature is evident		
✓ Signature to content binding is evident		
✓ Content is un-altered		
✓ Context is evident		
✓ Completeness (or not) is evident		
✓ Update(s) to original content are evident		
✓ Chain of Trust (from source to use) is		

evident		
✓ From origination to use		
✓ Transformation(s) are evident (e.g., to/from exchange artifacts)		
✓ Original “Source of Truth” is evident		

- 4A.** The Advisory makes no mention of the unique truth/trust predicate relationship (trust relies on truth) however this objective is paramount and should be made entirely explicit. There can be no claim to interoperability without basis in truth (evidence of authenticity) and resulting in trust (assurance). [See further discussion in Comment #7/7A.]

5. Interoperability Relies on Data/Record Integrity and Traceability

The source of truth is content captured at the point of health data/record origination. This is the anchor point for the chain of trust and is crucial to the achievement of interoperability. This is undisputable. For primary use – clinical care, interventions and decision making – the source of truth is unaltered source health data/record content. The receiving provider will first and always trust (rely on) this direct evidence of clinical facts, findings and observations.

Data integrity (including fidelity to source) is fundamental to all aspects of clinical integrity and most importantly, patient safety. From the perspective of the end user, the chain of trust starts at the point of health data/record origination/capture and continues to each point of access/use, traceably and without interruption. The Advisory should make this explicit.

ONC Interoperability, Final Version, page 73: “Individuals and providers should work together to routinely aggregate and reconcile electronic health information from multiple data sources to ensure accuracy and completeness of medical records.”

6. Interoperability as an Affirmative Trust Decision

As described above, the affirmative decision to trust and use health data/records received is one ultimate signal of achievement (of interoperability). Each ultimate end user takes responsibility as an individual or organization to make a “trust decision” regarding the veracity of health data/record content received and whether/when to use such information as the basis for subsequent clinical care, interventions and decision making (in primary use) or for other purposes.

- 6A.** The Advisory makes no mention of the affirmative trust decision but clearly the end user of health data/record content subject to the constraints of “best available” standards must be able to make that trust decision every time before electing to use such content.

Please update the Advisory to make this explicit.

7. Vital Properties/Qualities of Interoperability

What are vital properties or qualities of health data/records that demonstrate (achievement of) interoperability to the end user? Consider what we we’ve learned from our experience with intra-enterprise integration...

Intra-Enterprise integration enables interoperable health data/record content...		Qualities Manifest to End User
A	Known and verified as to identity: • Subject: patient • Provider: individual and organization • Author of health data/record content	Identified, Attributed, Evident as to Responsibility
B	Captured, consolidated from multiple sources within the enterprise	Unified, Integrated
C	Oriented to support real-time care delivery	Timely, Ready
D	Oriented to what has happened (past), what is now in progress (present), what is anticipated (future)	Chronological, Longitudinal
E	Oriented to who did what when	Accountable
F	Tuned for consistency: e.g., data types, common units of measure, codes and value sets	Uniform
G	Tied to the “source of truth”, showing provenance at point of data/record origination and thereafter	Factual, Authentic, Traceable
H	Bound to source, author’s signature	Authenticated
I	With known context: clinical, administrative, operational	Contextual
J	Known to be unaltered since origination	Immutable
K	Known to be complete – or known to have missing elements	Whole or Partial
L	Known to be original – or known to be updated from original instance	Original/Revision Progression
M	Associated with like information	Correlated, Comparable

- 7A.** As with the 2015 version, this is where the Advisory seems a disconnected universe. The Advisory fails to enumerate “best available” standards which are designed and capable to deliver even a basic subset of these vital properties.



Please revise the Advisory to make explicit which “best available” standards are built to deliver/evidence these properties (qualities) to each ultimate end user once (particularly after the point when) exchanged health data/records are subject to the constraints of these many standards.

8. Interoperability Access/Exchange Methods, Initiators and Limitations

Let’s look at three possible methods of achieving health data/record access (if not interoperability) – as beheld by the end user. Each method has a specific type of initiation and each method has limitations in terms of scope of data availability. Methods B & C rely on system-to-system exchange to convey data/records to the end user, whereas Method A takes the end user to the source system where data/records are already likely integrated and thus interoperable (but only within that domain).

	Method	Initiated by...	Limitations
A	Allow End User Direct Access to Source Domain	• Login to initiate user session	• Limited to health data/records available in source domain
B	Push Source Data to End User Domain	• Source trigger event	• Limited to data pushed • May be missing full context
C	Pull Source Data to End User Domain	• Receiver trigger event or • User inquiry	• Limited to data pulled • May be missing full context

For each method (A-C), the following shows the end user and their domain of access to health data/records.

	Source Domain (likely) Integrated/"Interoperable"	End User			Receiver Domain	End User
A	<u>Direct Access</u>					
B	<u>Push</u>	→	→	→		
C	<u>Pull</u>	←	←	← Query		
	Response →	→	→	→		

- 8A.** Presuming the scope of Advisory recommendations are limited to the “interoperability space”, it would seem that the Source (if not Receiver) Domain(s) are themselves out of scope. As noted in our comments on the 2015 version, it is obvious that recommended vocabularies, terminologies and code sets, if implemented natively (in Source and Receiver systems), would make interoperability much easier to achieve. Please revise the Advisory to make this explicit.

9. Evidence of Interoperability and the Affirmative Trust Decision

Establishing truth and trust as a key foundation for interoperability leads us to consider the current repertoire of standards-based exchange artifacts (messages and documents) and to examine their capability to convey key elements of truth (upon which end user trust can be based). The following table poses key questions/ challenges in our quest to substantiate the end user trust decision.

Truth (at source)	Exchange Artifact	Receiver
✓ Identity is verified	Is identity conveyed?	Within common identity domain? Is identity manifest?
✓ Source, origination and provenance is evident	Is it conveyed?	Is it manifest?
✓ Signature is evident	Is signature conveyed?	Is signature manifest?
✓ Signature/content binding is evident	Is signature/content binding conveyed?	Is signature/content binding manifest?
✓ Content is un-altered	Is non-alteration conveyed?	Is non-alteration manifest?
✓ Context is evident	Is context conveyed?	Is context manifest?
✓ Completeness (or not) is evident	Is completeness/ incompleteness conveyed?	Is completeness/ incompleteness manifest?
✓ Update(s) to original content are evident	Are updates conveyed?	Are updates manifest?
✓ Chain of Trust is evident	Is Chain of Trust conveyed?	Is Chain of Trust manifest?
✓ From origination to use		
✓ Transformation(s) are evident (e.g., to/from exchange artifacts)	Are transformations conveyed?	Are transformations manifest?
✓ Original “Source of Truth” is evident	Is original “source of truth” conveyed?	Is original “source of truth” manifest?

Most objective observers agree that the current set of Standards-based exchange artifacts fall far short of conveying necessary truth attributes – to say nothing of the limitations of receiving systems to manifest those attributes – to the end user who must make a trust decision.

- 9A.** [See Comment #4/4A.] Please revise the Advisory to make explicit which “best available” standards are built to deliver these vital truth attributes to each ultimate end user once (after the point when) conveyed/received health data/records are subject to the constraints of these many standards.

10. Interoperability via Transformation and Fragmentation?

As previously noted, substantial amounts of health data/record content are now captured – at the point of service or point of care – and retained in integrated provider EHR systems. This data is immediately available and seamlessly interoperable with a broad range of other information within that domain. The essential qualities of truth are established and the trust decision is most always affirmative. This is the case BEFORE exchange occurs.

We then take that same information and rend it from its integrated and interoperable habitat – slicing, dicing, fragmenting and transforming source health data/record content into the form and format required for the standards-based exchange artifact. Structured content becomes unstructured and vice-versa, data types are transformed, coded values are mapped (often incorrectly, or even if correctly, losing important context) into the classification conventions of various external code/value sets and vocabularies. Data is mapped one to many and many to one. Some source data attributes lack corresponding attributes in the exchange artifact and must be dropped. Some codes have no equivalent value and are not included.

In patient summary oriented exchange artifacts (e.g., HL7 CCD), data relationships are often sundered. For example, chronologies, trends and relationships between encounters, problems, diagnoses, orders, medications, results, diagnostics, interventions, observations, therapies and care plans are lost or become unrecognizable.

And so far we’ve only described what happens on the source/sending side of exchange. On the receiving side, all of the above slicing, dicing, fragmentation and transformation occurs once again.

- 10A.** In line with our comments on the previous version, there should be careful consideration of the extent to which the recommended “best available” standards actually require/promote slicing, dicing, fragmenting and transforming health data/record content from its source representation – as opposed to leaving source content in its original unaltered form – or at least carrying the original content alongside the transformed content.

11. Interoperability Maintains Content/Context Relationships

It is a simple fact that transformations to/from exchange artifacts often create (introduce) alterations, omissions and errors in health data/record content. Data items that were integrated and seamlessly interoperable in the source system are no longer so. Data once fit for primary (clinical) use may now only be fit for secondary use (or not).

As an industry we’ve also demonstrated that in practice, standards-based exchange artifacts mostly yield to the lowest common denominator benchmark. This has proven sufficient to support some narrowly limited health data/record secondary uses but not primary use (clinical care, interventions and decision making).

Health data/record fragmentation, transformation and loss of context are real barriers to interoperability.

- 11A.** As a key patient safety and clinical practice integrity issue, it is critical that key health data/record content and context relationships remain intact and that “best available” standards are built to include/convey these content/context relationships to each ultimate end user once (after the point when) conveyed/received health data/records are subject to the constraints of those standards.

Please revise the Advisory to make explicit which “best available” standards are designed and capable to deliver intact vital clinical context/content relationships from source health data/records (particularly for primary uses and users).

12. Proper Scope of Interoperability for Health Data/Records


Interoperability is not something that finally comes into play once data is transformed to exchange artifacts and queued for transmission to an external system (at point of exchange). As described in Comment #7, key qualities of health data/records are essential and must be in place before exchange artifacts are created or exchange itself occurs. Most of these qualities (e.g., source/authorship, provenance, attestation, non-alteration) are either captured at the data/record source or are intrinsic to data/record management up to the point of exchange. In addition, the transformative processes essential to take many disparate sources and convey that information, while maintaining the relevant trust attributes, into a multi-source, useable and useful integrated representation around each individual are fundamental to effective interoperability.

It is clear that a valid interoperability scheme for health data/records must invariably start at the source – point of data/record origination – and continue uninterrupted to each ultimate point of access/use, potentially traversing one or more points of exchange along the way and resolving itself in the final outcome to an integrated individual health record.

- 12A.** As with the prior version, we strongly suggest ONC expand the scope of its “interoperability” definition to start at the point of health data/record origination. This is the key anchor point (source of truth) for health data/record interoperability. Encompassing the source of truth may be without risk or otherwise ignored in other industries, but we cannot take that stance in support of individual health and provision of healthcare (while ensuring patient safety and clinical integrity).

13. Interoperability Enabled by the Chain of Trust

In previous comments we have described the convergence of integration, truth and trust as vital pillars to support/achieve health data/record interoperability. The following table offers an end-to-end perspective from point of data/record origination to each ultimate point of data/record access/use. Information flow is traceable via a “chain of trust”, itself enabled by the succession of audit and provenance events that capture related metadata. In this example, health data/record flow is top to bottom.

Health Data/Record Chain of Trust from Point of Origination to each Point of Access/Use					
Flow	Point of Health Data/Record...	(For primary clinical use)	Audit Event	DPROV Event	Original Content (primary use)
Source System					
↓	Capture, Origination • Source of Truth • Anchor Point for Chain of Trust	<ul style="list-style-type: none"> Clinical facts, findings and observations are captured Clinical context is captured Provenance is captured: <ul style="list-style-type: none"> Who, what, when, where, why Identities are established: <ul style="list-style-type: none"> Patient: subject of care Provider: organization, individual Author of data/record content 	X	X	Is captured
↓	Retention	Of Source Record Entry	X		Is retained
↓	Attestation	<ul style="list-style-type: none"> Application of Signature Bound to data/record content 	X	X	Is attested/signed
↓	Transformation	From Source Record Entry to Exchange Artifact: e.g., HL7 message or document	X	X	Is carried
↓	Transmission	Of Exchange Artifact	X		Is carried
Receiving System					
↓	Receipt	Of Exchange Artifact	X		Is carried
↓	Transformation	From Exchange Artifact to Receiver Record Entry	X	X	Is carried
↓	Retention	Of Receiver Record Entry	X		Is retained
↓	Access, view • Trust Decision	By End User 	X		Is accessed, viewed

The Chain of Trust is shown as successive Events (2nd/3rd column) in health data/record management – starting at the point of origination (the “source of truth”). Audit Events (4th column) are captured at each Event. With this metadata the Chain of Trust traces source health data/record content and its path to each ultimate end user/use. Data Provenance Events (5th column) capture related metadata at Events when health data/record content is new or updated. Primary Use requires original data/record content to be evident at each ultimate point of data/record access use (6th column) and is a paramount success factor to achieving health data/record interoperability. The Chain of Trust provides evidence for the Trust Decision by each ultimate end user.

[AuditEvent and Provenance are two HL7 Fast Health Interoperability Resources (FHIR), currently part of FHIR DSTU-2 and profiled together in the HL7 FHIR Record Lifecycle Event Implementation Guide, also published as part of FHIR DSTU-2.]

- 13A.** Adding a new category to “best available” standards, please revise the Advisory to include end-to-end chain of trust, health data/record management from point of origination to each ultimate point of access/use or deletion/destruction (lifespan) including events likely to occur

within that lifespan (lifecycle). The following standards are directly applicable and should be included:

- ISO 21089, Trusted End-to-End Information Flows (first published 2004, currently in revision)
- ISO/HL7 10781, Electronic Health Record System Functional Model, Release 2 (2015)
- ISO/HL7 16527, Personal Health Record System Functional Model, Release 1 (2015)
- HL7 EHR Lifecycle Model DSTU (2008)

[See additional details and recommendations in Comments #14-17 following.]

14. Interoperability Relies on Audit, Provenance and Traceability

As noted in previous comments, much of what makes interoperability evident is the coupling of audit logs, provenance and traceability.

Since May 2014, an HL7 Project Team has focused on health data/record lifespan – and lifecycle events occurring within that lifespan – in context of implementations using HL7 Fast Healthcare Interoperability Resources (FHIR). Record lifecycle events include: originate, retain/maintain, update/amend, verify, attest, translate/transform, disclose, transmit, receive, archive, delete/destroy and more. The Team started with Standards-based requirements (for audit, provenance, traceability and more) and profiled FHIR AuditEvent and Provenance resources to capture applicable metadata at each lifecycle event. Resulting from this effort is a new Record Lifecycle Event Implementation Guide (RLE IG) for HL7 FHIR.

Consistent, broad-based adoption of fundamental audit, provenance and traceability for health data/records is essential to any interoperability solution.

Please include the following HL7 FHIR Implementation Guide in the Advisory:

- HL7 Record Lifecycle Event Implementation Guide, part of FHIR DSTU-2
Based on EHR-S FM Record Infrastructure Chapter, Record Entry Lifespan and Lifecycle
(published September 2015)
<http://hl7.org/fhir/ehrsrle/ehrsrle.html>

- 14A.** As referenced in Comment #13A, please use this new category to include Advisory “best available” standards recommendations for audit, provenance and traceability. Include the standards listed in Comment #13A.

15. Interoperability Relies on End-to-End Standards

Reference: ISO 21089, Health Informatics – Trusted End-to-End Information Flows

Interoperability relies on trusted end-to-end management of health data/records from the point of origination to each ultimate point of data/record access/use, encompassing data at rest and data in motion. This Standard is agnostic as to the type of system (EHR, PHR, HIS, Ancillary or other system), but rather as to its system role in end-to-end information flow. This Standard provides guidance for US and international communities, promoting a common infrastructure and uniformity in management of end-to-end information flow implementations worldwide.

International Standards for trusted end-to-end information flows focus on universal solutions for health data/record interoperability.

- 15A.** As noted in Comment 13A, please include ISO 21089 in the list of “best available” standards for health record capture, retention, end-to-end record lifespan and lifecycle management, audit, provenance and traceability.

16. Interoperability Relies on EHR, PHR (and other) System Functionality Standards

Reference: ISO/HL7 EHR/PHR System Functional Models

Interoperability relies on common constructs and functional support for health data/record capture, update, retention, management and exchange. The ISO/HL7 Functional Model Standards provide guidance for US and international communities, promoting common functionality between and across EHR and PHR systems. For example, the EHR-S FM Record Infrastructure Section describes basic record management functions for EHR record entries, including functions to support record entry lifespan and lifecycle.

Key international Standards for EHR/PHR system functionality provide a common framework for interoperability, both US and worldwide.

- 16A.** The Advisory is silent on EHR, PHR and other system functions necessary to support interoperability and in fact utilize the enumerated “best available” standards. Please include both ISO/HL7 system functional models and the following HL7 Functional Profiles in the Advisory:
- ISO/HL7 10781 Electronic Health Record System Functional Model, Release 2
aka EHR-S FM (published by HL7 2014, ISO 2015)
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269
 - ISO/HL7 16527 PHR System Functional Model, Release 2
aka PHR-S FM (published by HL7 2014, ISO 2015)
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=88
 - HL7 Meaningful Use Functional Profile for Stages 1&2
Based on ISO/HL7 10781 EHR-S FM (published 2015)
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=409
 - HL7 Public Health Functional Profiles, suite of nine (9) FPs for specific public health services/domain areas, developed in collaboration with the Centers for Disease Control and Prevention (CDC)
Based on ISO/HL7 10781 EHR-S FM (published 2015)
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=278

17. Interoperability From/To Provider Business/Legal Records

With the advent of enterprise-wide EHR Systems, most all of the provider health data/record is there committed. This record serves:

- A. Business purposes – as a an account of operations, processes and services provided;
- B. Legal purposes – as evidence of who did what when, which may be attested for purposes of accountability and substantiation (e.g., of claims for payment) and as the legal record for reporting, administrative and court proceedings;
- C. Professional/clinical purposes – as an account of actions taken by providers in support of individual health and provision of healthcare.

Most providers take great care to ensure their business/legal record is precise, accurate, complete and properly maintained. The business/legal record is a chronicle and key asset of every health provider enterprise.

In April 2013, the HIT Policy Committee offered a set of recommendations for ONC consideration of “legal health record”. The recommendations offered the basis for a “legal health record” framework as (in part) an underpinning for nationwide interoperability of health data/records from/to enterprises with established business/legal record systems.

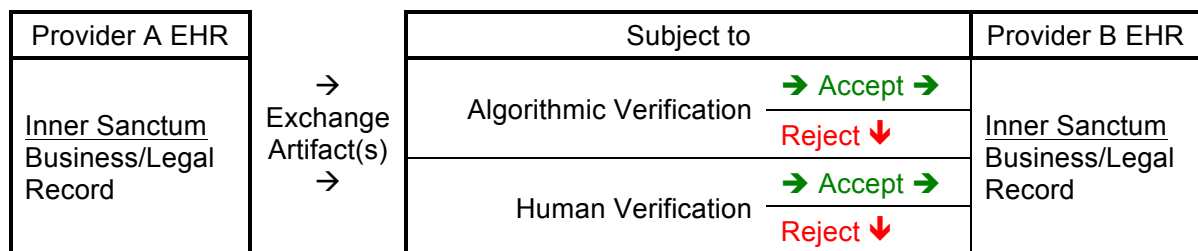
[To date, ONC has taken no visible action on the HITPC recommendations.]

Provider business/legal records are the foundation for trusted and interoperable end-to-end information flow. Included are all parties engaged in, and accountability for, enterprise operations, processes and services provided.

- 17A.** The Advisory makes no mention regarding if/how the recommended “best available” standards serve to support the provider health record as a business/legal record. Please revise the Advisory to make this explicit and reference the standard set offered in Comment 13A for this “given interoperability need”.

18. Interoperability Doesn’t Require Manual Interception before Committal

A basic challenge for most providers capturing exchange artifacts from external sources is acceptance (acceptability) criteria including what to accept automatically – algorithmically verified but without human review. They maintain meticulous control within their enterprise and must ensure their pristine, carefully curated business/legal record is safeguarded and not contaminated by invalid/incomplete/disjoint data/record content from external sources. The following shows a typical pattern of exchange:



In most cases, algorithmic verification always precedes human verification. Competent human review is costly, increasing in time/cost as more inbound data/records are received. Human review may still be inconclusive (e.g., often the human has no access or ability to compare inbound content to original source content). The Advisory is silent on the current challenge of inbound data quality and the need for human review.

Data quality and integrity issues include accuracy, consistency, context, completeness and more. Lack of inbound data quality and limitations of software algorithms and even human review stand as serious and thus-far unresolved barriers to interoperability.

- 18A.** We believe careful consideration should be given as to whether the set of recommended “best available” standards overcomes or instead increases/aggravates the challenge(s) of inbound data quality/integrity to receiving entities. Standards lacking basic data quality protections (e.g., carrying original content alongside transformed content) might be “available” but may not be “best” in this context.

19. Interoperability Relies on Common Constructs

One of the best paths to interoperability is to open the breadth of common constructs between source and receiver systems. In 2011, the S&I Simplification Work Group was formed as a volunteer Initiative under the Standards and Interoperability Framework (S&I). This WG has taken 20 mostly heterogeneous S&I Use Cases, with 44 different Scenarios, and analyzed each for elemental and common constructs, including:

- Requirements: incl. Assumptions, Pre/Post Conditions, System Functional Requirements
- Actors and Roles
- Scenarios, Events and Actions
- Data Objects and Elements

A substantial set of common constructs were identified and are now catalogued in the S&I Simplification Core Matrix v3.3, in the AHRQ-hosted US Health Information Knowledgebase (USHIK) and in the Federal Health Information Model (FHIM).

Work products of the S&I Simplification Work Group are found here:

<http://wiki.siframework.org/Cross+Initiative+-+S%26I+Simplification+WG>

<http://wiki.siframework.org/Use+Case+Simplification+Reference+Materials>

- 19A.** Work of the S&I Simplification Work Group shows the many advantages of exploiting commonalities across use cases, building on basic/common constructs and facilitating interoperability of health data/records. Please revise the Advisory to include a new category for use case development and the management of patient, provider (work/process) and information flows, referencing:

- S&I Simplification Core Matrix, Version 3.3 (S&I Framework consensus document)
<http://wiki.siframework.org/file/view/ONC-SI-Simplification-Core-Matrix-v3-3-20141211.xlsx>
- ISO 19669, Re-Usable Component Strategy for Use Case Development (ISO TC215 Working Draft)